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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,558	07/17/2001	Stefan Dietmar Anker	ICI 102	9145

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/807,558	**Applicant(s)** ANKER ET AL.	
	Examiner Fozia M. Hamud	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *07 November 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-4,19 and 29-31*.
   Claim(s) withdrawn from consideration: *5-18 and 20-27*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Eileen B. O'Hara

EILEEN B. O'HARA
PATENT EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: The amendment to the claims submitted on 21 November 2005 has been entered. Applicants submit arguments regarding the rejection against claims 1-4, 19 ad 29-31 made under 35 U.S.C 112, first paragraph, however, most of the arguments had been addressed in the previous office actions. Applicants contend that now that the mechanism of treatment of cachexia is known, one of ordinary skill can adjust doses for a particular patient. This is not found persuasive, because the agents to be adminstered are only described as having the ability to decrease SNS activity, which encompasses destructive agents that may kill or destroy all SNS activity. Neither the specification nor the claims disclose how low should SNS activity be reduced. Furthermore, the instant specification fails to disclose specific drugs, dosage, regimen or results for the claimed method. Applicants' argument that it is not necessary for them to explain drug compatibility, since the skilled person already assesses routinely on a patient to patient basis, is not found persuasive, because the instant claims are drawn to a method of treatment of patients that are suffering from a chronic disease or emotional disturbance, therefore, it is apparent that these patients are already being treated for these diseases. Accordingly, it is the specification, not the knowledge of the skilled artisan that should supply the novel aspects of the claimed invention, in order to satisfy the enablement requirement, (Genetech, inc v. novo nordisk 42 USPQ2Dd at 1004).

Regarding the rejection of claims 1-4 and 19 made under 35 U.S.C 112, first paragraph as failing to meet the written description requirement, Applicants are right in that "all possible" compounds that reduce SNS activity do not have be disclosed, but the claimed genus must be satisfied by disclosing a representative number of species, and the instant specification fails to do so. The agents to be administered are described by function alone, there is no disclosure of a correlation between a structure and the recited activity. Since there is no common structure for all of the encompassed agents and there is no one single art recognized class of compounds, the skilled artisan would not recognize that all of the encompassed compounds would be useful in the claimed method.

Regarding the rejection of claims 1-4, 19 and 29-31 made under 102 (b) as being anticipated by the RALES study, Applicants contend that the population in the RALES study is not the same as the population specified in the instant claims. Applicants also argue that RALES does not disclose or suggest of selecting patients with cachexia. This is not found persuasive, because although not all patients with heart failure have cachexia, some do. Therefore the population treated with spironolactone in the RALES study is not explicitly excluded as having cachexia. Accordingly, since the patient population is the same as the one recited in the instant claims and the agent administered is one that reduces SNS activity, the RALES study meets all the limitations recited in the claims..

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